DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-851/S-021

Novartis Pharmaceuticals Corporation
Attention: Mr. Carl Schlotfeldt
59 route 10
East Hanover, NJ 07936-1080

Dear Mr. Schlotfeldt:

Please refer to your supplemental new drug application dated June 27, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotensin (benazepril HCl) Tablets.

We acknowledge receipt of your submission dated July 18, 2001 that constituted a complete response to our April 18, 2001 action letter.

This supplemental new drug application provides for final printed labeling revised to add an additional paragraph to the current statement on geriatric use under **PRECAUTIONS/Geriatric Use**, as follows:

> Of the total number of patients who received benazepril in U.S. clinical studies of Lotensin, 18% were 65 or older while 2% were 75 or older. No overall differences in effectiveness or safety were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.
>
> Benazepril and benazeprilat are substantially excreted by the kidney. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

We note that minor editorial changes have been made.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Ms. Sandra Birdsong
Regulatory Health Project Manager
(301) 594-5334

Sincerely,

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Raymond Lipicky

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